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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/784,949	02/15/2001	Arthur Campbell	PD-0387	4193

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EXAMINER

LAM, ANN Y

ART UNIT PAPER NUMBER

1641

DATE MAILED: 10/03/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/784,949

Applicant(s)

CAMPBELL ET AL.

Examiner

Ann Y. Lam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) ^{1-22 and 24-54} ~~1-54~~ is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) ^{1-22 and 24-54} ~~1-54~~ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 3-10, 12 and 15-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Peterson et al., 5,247,434.

As to claims 1, 42, and 43, Peterson et al. discloses a drive mechanism (72) that forces the fluid out of a reservoir; a housing sized to be carried by the user and adapted to contain at least a portion of the reservoir and the drive mechanism; an input device coupled to the housing, see column 9, line 58; a processor contained in the housing (504); a display coupled to the housing (see column 5, line 45 for example) that receives information from the processor and visually displays one or more screens containing the information; wherein at least one of the one or more screens includes a menu with at least two menu items, wherein the input device is used to select one menu item from amongst the at least two menu items, and wherein selection of one of the at least two menu items causes the display to show at least another one of the one or more screens that is a set screen including a plurality of control parameters associated with the selected menu item, and further wherein the set screen guides the individual through sequential steps for programming the plurality of control parameters associated

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with the selected menu item, and wherein the input device is used to program the plurality of control parameters associated with the selected menu item from the set screen, see column 8, line 67 – column 9, line 3, and column 9, lines 11-29, and column 9, line 58 – column 10, line 3, and column 11, lines 28-39.

As to claims 3, 18, 39 and 40, the system includes a means (504) to store a maximum bolus that is programmable using the input device, see column 17, lines 29-33, and column 22, line 35, wherein the maximum bolus limits the maximum units of fluid that can be delivered in a single bolus.

As to claims 39 and 40, the bolus is considered to be an express bolus or an easy bolus.

As to claims 4 and 17, the system includes a means to store a maximum basal rate as claimed, see column 17, lines 60-63.

As to claims 5, 47, 48, 49, 50, the system includes a means to store one or more basal profiles as claimed, see column 17, lines 60-63.

As to claim 6, the system includes one or more alarm types as claimed, see column 21, lines 15-19.

As to claims 7 and 20, the system includes a means (504) to store an insulin type.

As to claims 8 and 21, the system includes a means (504) to store a reservoir type as claimed.

As to claims 9, 10, selection of one of the two menu items causes the infusion system to reset the control parameters to factory default values, see column 33, lines 16-19.

As to claim 12, at least one of the menu items causes the drive mechanism (72) to reverse direction.

As to claims 15 and 41 the screen is considered to be a status screen.

As to claims 16 and 19, the one or more screens is considered to include one or more set or select screens that is a set screen including a single control parameter associated with the selected menu item, and wherein the input device is used to program the single control parameter associated with the selected menu item from the set screen, see column 9, line 15-16.

As to claim 22, the one or more select screens is considered to include a screen to select a language.

As to claims 23 and 24, a housing, infusion set and tubing as claimed is disclosed, see column 2, lines 57-62.

As to claims 25 and 26, a manual prime or a fixed prime may be used to fill the tubing with fluid from the reservoir, see column 11, lines 37-39.

As to claim 27, the information is shown on the display screen to guide an individual through the steps to prime the infusion system as claimed, see column 11, lines 28-38.

As to claim 28, one of the at least two menu items is highlight when the menu is displayed, see column 11, lines 28-32.

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As to claim 29, the one of at least two menu items that is highlighted when the menu is displayed is considered dependent on a function that the infusion system is performing when the menu is displayed as claimed, see column 11, lines 28-39.

As to claim 30, the system further includes a communication device for receiving communications from an external device to control the drive mechanism, see column 13, lines 38-41.

As to claim 31, selection of at least one of the at least two menu items causes the display to show a screen that allows an individual to signify the identity of a device, which thereby configures the infusion system to accept communication from the device, see column 13, lines 55-64.

As to claim 32, the input device includes a keypad, see column 9, line 49.

As to claim 33, when the infusion system is suspended from delivering fluid, fluid delivery is resumable with two or less keystrokes independent of the screen being displayed, see column 32, lines 40-50.

As to claim 34, the ENTER/CLEAR, see column 9, line 18, is equivalent to an ACT key as claimed.

As to claims 35 and 36, the ENTER/CLEAR key, see column 9, line 18, is equivalent to an Esc key as claimed.

As to claims 37 and 38 a single keystroke is used to exit a Blank Screen and display at least one other screen, such as a Main Menu screen, see column 9, line 49.

As to claim 44, the screen is considered to select a therapy.

As to claim 45, the input device is considered to include soft keys.

As to claim 46, the screen is considered to be a confirmation screen.

As to claims 51-54, the menu items include square wave bolus or dual wave bolus as claimed, see column 9, lines 30-45.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Peterson et al., 5,247,434, in view of DeLaHuerger, 6,408,330.

Peterson et al. discloses the invention substantially as claimed, except for the processor running energy management software that changes the display to a Blank Screen after a Time-Out delay has expired.

DeLaHuerger discloses a drive mechanism, see column 17, line 51, an input device, a processor (194), a screen (523) with a menu, see column 29, lines 62-64, as claimed, wherein the processor runs energy management software that changes the display to a Blank Screen after a Time-Out delay has expired, see column 25, lines 22-34. It would have been obvious to provide this feature in the Peterson et al. device as taught by DeLaHuerger.

3. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Peterson et al., 5,247,434, in view of Say et al., 6,175,752.

Peterson et al. discloses the invention substantially as claimed, see above, except for the alarm intensity changing with time.

Say et al. discloses a drive mechanism (260), an input device (162), a processor, a screen and menu, see column 53, lines 226-27, as claimed. As to claim 11, the system includes an alarm wherein the alarm intensity changes with time, see column 46, lines 9-23. It would have been obvious to provide an alarm that changes intensity with time, as taught by Say et al., as would be desirable for an alarm.

4. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Peterson et al., 5,247,434, in view of Benkowski et al., 6,183,412.

Peterson et al. discloses the invention substantially as claimed, see above, except for the system performing a selftest.

Benkowski et al. discloses a drive mechanism (12), a processor (80), an input device, a screen and menu, see column 12, lines 38-4, as claimed. As to claim 13, selection of at least one of the at least two menu items causes the infusion system to begin a selftest, see column 5, lines 51-52. It would have been obvious to provide a menu that causes the Peterson et al. system to perform a selftest as taught by Benkowski.

5. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Peterson et al., 5,247,434, in view of Havel, 5,003,298.

Peterson et al. discloses the invention substantially as claimed, see above. However, Peterson et al. does not disclose a numeric value displayed on the screen

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wherein a number to the right of a decimal point is formatted differently than a number to the left of the decimal point.

Havel discloses a display wherein the digits that precede the decimal point are illuminated in a first color, and digits that follow the decimal point are in a second color, to more effectively emphasize the position of the decimal point, see column 1, lines 47-52, and column 3, lines 51-58. The number to the right of the decimal point is considered to be formatted differently than a number to the left of the decimal point. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide in the Peterson et al. system the format for the digits to the right and left of a decimal point as taught by Havel in order to emphasize the position of the decimal point for easier reading.

Response to Arguments

Applicant's arguments filed September 8, 2003 have been fully considered but they are not persuasive.

Applicant argues that the Peterson et al. reference does not guide the user through sequential steps to program a plurality of control parameters, such as sequential steps of programming the heparin pump rate, followed by the dialysate flow rate or the dialysate temperature, see page 13. Applicant notes that the Peterson et al. reference discloses that the user may select a parameter to be programmed by touching a corresponding button, enter a value for the parameter using a pop-up keypad, and then confirm the modified parameter by pressing another button. Applicant

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further notes that the Peterson et al. reference also discloses that the user may program a profiled parameter by tracing a desired profile curve on the touch screen, and the computer will then display a series of bars corresponding to the traced curve, which the user may confirm by pressing a button. Examiner asserts that these features are "control parameters" through which the Peterson et al. device guides the user. That is, the term "control parameters" claimed by Applicant does not exclude these features from being control parameters.

Applicant also argues that the Peterson et al. reference does not include a drive mechanism that forces fluid out of a reservoir, a housing sized to be carried by the user and adapted to contain at least a portion of the reservoir and the drive mechanism, etc. Applicant argues that the Peterson et al. reference is neither capable of being carried, nor even intended to be carried by a user, see page 14. Examiner asserts that Applicant has not specified in the claims how the housing is to be carried by the user, and that in any case, the housing is capable of being carried by the user. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

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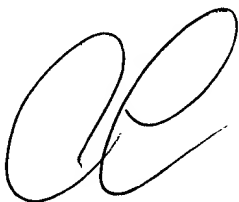
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703)305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

A.L.



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09/26/13